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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,882	10/01/2001	Montague Cecil Solomon	6969	7981

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1615	5

DATE MAILED: 07/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,882	SOLOMON ET AL.	
	Examin r	Art Unit	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4, 6, and 7 is/are rejected.

7)☒ Claim(s) 5 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

2. Claim 6 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

3. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In order to render the claim complete, the applicant must clearly state the limitations of the given examples within the body of the claim, so as to establish definite metes and bounds. See MPEP § 2173 and § 2173.02. It is unclear what the applicant intends by the phrase "substantially as herein described in any of the Examples", whether the limitations of the claim are drawn to specific components used, specific quantities of components, and/or particular method steps.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Maeda *et al.* (EPO Document No. 0 276 561 A1)

The Maeda *et al.* document discloses a method for the preparation of a pharmaceutical tape composition (See Page 2, Lines 1-5). This preparation involves first adding an alkaline agent to the active substance and optionally dissolving and dispersing the mixture with an organic solvent, and then blending the resulting mixture with an adhesive base (See Page 3, Lines 25-27 and 46-51). Crotamiton is listed as a preferred solvent and may be present in amounts up to 20 parts by weight of solvent to one part of piroxicam, the active substance (See Page 3, Lines 27-37; and Page 5, Example 2). Although the method in the Maeda *et al.* document discloses that the piroxicam is first preferably dissolved in an aqueous agent of an alkaline agent, followed by the addition of the organic solvent, the document nevertheless states that the piroxicam/alkaline solution is further dissolved and dispersed into the solvent, which reads on the claims of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda *et al.*

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The Maeda *et al.* document discloses a method for the preparation of a pharmaceutical tape composition (See Page 2, Lines 1-5). This preparation involves first adding an alkaline agent to the active substance and optionally dissolving and dispersing the mixture with an organic solvent, and then blending the resulting mixture with an adhesive base (See Page 3, Lines 25-27 and 46-51). Crotamiton is listed as a preferred solvent and may be present in amounts up to 20 parts by weight of solvent to one part of piroxicam, the active substance (See Page 3, Lines 27-37; and Page 5, Example 2). Although the method in the Maeda *et al.* document discloses that the piroxicam is first preferably dissolved in an aqueous agent of an alkaline agent, followed by the addition of the organic solvent, the document nevertheless states that the piroxicam/alkaline solution is further dissolved and dispersed into the solvent, which reads on the claims of the instant application.

6. Claims 1, 3, 4, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins (U.S. Patent No. 5,352,457).

The Jenkins patent teaches a method of preparing a device for the transdermal administration of a drug (See Abstract). A portion of the preparation process involves dissolving the active ingredient in a solvent mixture and then adding the polymer adhesive solution (See Column 2, Line 50 to Column 3, Line 51). Diethyltoluamide (DEET) is listed as a preferred solvent, and several preferred solvent systems are given which comprise diethyltoluamide (See Column 4, Lines 2-21). Oestradiol (estradiol) is given as a possible active ingredient to be included in the transdermal device (See Column 4, Lines 25-26). Example 1 of the patent describes the preparation process where the active ingredient is dissolved by sonication or warming in a solvent system comprising diethyltoluamide, and the resulting mixture is added to an aqueous acrylate adhesive dispersion. Based on the wording of the phrase "a thicker spreading solution" (See Column 6, Lines 40-41) and its context, one of ordinary skill in the art can infer that the resulting mixture of active ingredient, solvent, and adhesive resulted in a solution. Example 2 describes a similar process using oestradiol as the active ingredient. Although the patent discloses that the mixture is then dried into a film in which the active ingredient exists in a saturated or supersaturated state, it would be obvious to one of ordinary skill that the active ingredient possibly and perhaps likely exists in a state below its saturation point before the drying step occurs.

7. Claims 1-4, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda *et al.* and Jenkins and further in view of Hirano *et al.* (U.S. Patent No. 5,820,878)

Maeda *et al.* disclose a method of preparing a pharmaceutical tape composition, as discussed in the rejection of Claims 1, 2, and 7 under 35 U.S.C. 102 and 103 *supra*. Jenkins teach a method of preparing a device for the transdermal administration of a drug, as discussed in the rejection of Claims 1, 3, 4, and 7 under 35 U.S.C. 103 *supra*. Maeda *et al.* do not disclose the use of diethyltoluamide as a solvent component or the use of estradiol as the active ingredient. Jenkins does not teach the use of crotamiton as a solvent component.

The Hirano *et al.* patent teaches a percutaneously absorbable patch comprising estrogen and luteal hormones (See Abstract). Estradiol is given as a particular example of an estrogen (See Column 2, Lines 10-14), and it can be present in an amount ranging from 0.01% to 10% of the total weight of the pharmaceutical preparation (See Column 2, Lines 20-23). Crotamiton is discussed as an important component of the preparation, particularly its ability to enhance the active substances, in terms of solubility, release from the preparations, and percutaneous absorption (See Column 2, Lines 46-57).

It would be obvious to one of ordinary skill in the art to combine the teachings of Maeda *et al.*, Jenkins, and Hirano *et al.* into the object of the instant application. Both Maeda *et al.* and Jenkins teach methods of preparing a transdermal composition using steps which read on the claims of the instant application; Maeda *et al.* show methods using crotamiton, while Jenkins *et al.* teach methods using diethyltoluamide and estradiol. Hirano *et al.* teach transdermal compositions comprising estradiol and crotamiton. As discussed above, Jenkins teaches that diethyltoluamide is a preferred component of solvent systems used to prepare transdermal devices, including those comprising estradiol as the active substance. In addition, Hirano *et al.* discloses that solubility, release, and absorption of estradiol can be enhanced with crotamiton.

One of ordinary skill would be motivated, with a reasonable expectation of success, to create an estradiol transdermal composition further comprising crotamiton and diethyltoluamide, in order to take advantage of the beneficial properties of both chemicals combined into a single composition. Thus, the claimed invention, as a whole, is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Patent Examiner
AU 1615

sjo
July 3, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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